

Remarks

Claims 11-23, 25-28, and 30-33 are presented for consideration on their merits; claims 1-10 were previously cancelled, and claims 24 and 29 are cancelled by virtue of the instant Amendment.

In particular, the independent apparatus claims 11 and 23 have been amended to define that the coughing reflex occurs through stimulation of the pharynx. Method claim 22 has been amended to make it clear that the ultrasonic vibrations are applied to and penetrate the soft tissue portion of the neck of a person. Claims 31 and 32 are new, and stress applicant's invention in slightly different format and terminology.

With regards to the Examiners objections based on the prior art, the following comments are provided:

The Examiner argues that claims 11, 12 and 13 are obvious in view of the combination of Hughes, US patent No. 6058932, and Schechter, US patent No. 5058600.

Hughes US Patent No. 6058932

This invention disclosed in the Hughes patent clearly is not designed to induce a coughing reflex in a person. While the Examiner states that Hughes discloses an apparatus for inducing a coughing reflex in a living being, using ultrasonic wave generating means to stimulate a reflexive coughing action, the expressed purpose of the invention of Hughes is to use acoustic vibrations to loosen phlegm within the body, and not for the purpose stated by the Examiner. (emphasis added)

In Hughes, after the phlegm is loosened, the patient's energy is then required to expulse the phlegm by coughing. The device itself does not stimulate coughing. In addition the device of this invention uses an acoustic generator that is a generator which generates a sound wave or sonic wave (see for example the column 3, line 67 reference to an acoustic waveform which may be a continuous waveform or a series of sonic pulses

and column 5, lines 11 to 21 where reference is made to dampening of the sound signal). An acoustic signal is in the range of 20Hz to 20KHz whilst an ultrasonic wave is above the range of normal hearing, that is a frequency above 20KHz

The transducer of the Hughes device is also described at column 6, lines 41 to 46 as being a speaker or microphone. The frequencies referred to in column 8, lines 51 to 64 are also not ultrasonic frequencies, being in the range of 10Hz to 10000Hz.

While the Hughes description makes reference at column 4, lines 54 to 66, to an "ultrasonic signature", that terminology is used in reference to a signature produced by a patient's breathing around a mucous plug (see also column 12, line 42). That signature is used to trigger generation of acoustic waveforms.

As referred to in column 5, lines 1 to 6 of Hughes, the waveform of sound pulses is transmitted directly to the user's lungs to loosen the mucous, after which the user can cough to expel the loosed phlegm. The Hughes apparatus, however, does not, per se stimulate a reflexive coughing action.

The method and apparatus of the present invention, as expressed in the claims of record, are not for breaking up phlegm but for stimulating a coughing action by external application of ultrasonic vibrations to the neck of a person to penetrate soft body tissues of the neck and stimulate the pharynx to induce a reflexive coughing action.

This may be compared with the Hughes patent where there is a transmission of acoustic signals (that are non-ultrasonic signals) into the airways and lungs for breaking up mucous.

Hughes therefore does not disclose, or even suggest, the unique features of claims 11, 12 and 22 as asserted by the Examiner in clauses 2,3 and 4 of the Office Action.

Schechter US patent No. 5058600

Schechter discloses apparatus for monitoring patient breathing to determine airway obstruction. Schechter is not concerned with inducing a reflexive cough action in a person, nor with applying either an acoustic or ultrasonic signal to the neck or a body.

The Schechter apparatus uses acoustic monitoring of a patient's airway. Acoustic signals of airway noises are picked up using microphones (see column 2, lines 18 to 24). Only acoustic signals (that is sound signals) are monitored. The frequencies referred to in column 4, lines 47 to 61, column 5, lines 40 to 55 and column 6, lines 10 to 60 and monitored by the Schechter apparatus, are all below the ultrasonic range of frequencies, that is below 20Khz.

While Schechter users transducers (lines 3-8 column 3), the transducers are used to generate electrical signals corresponding to the acoustic vibratory pattern of the patients breathing. The transducers thus act as sensors to sense breathing pattern and provide signals corresponding to that pattern. The transducers of Schechter are not used to apply a signal to the neck of a patient as claimed in the current application.

As Schechter is used for detecting acoustic signals from breathing, and Hughes is used for applying acoustic signals to the airways through the mouth, it is submitted that the combination of those documents would not result in the invention as claimed in claims 11, 12 and 22. At most, a combination of Hughes and Schechter would result in apparatus in which acoustic signals are provided to the airways through the mouth and in which breathing could be monitored by an external acoustic monitor.

The Examiner further asserts that claims 13-21, 23-27 and 28 are obvious in view of the combination of Hughes, US patent No. 6058932, Schechter, US patent No. 5058600, and Erikson US patent

No. 5269747, but a closer reading of the citations reveals the anticipatory shortcomings thereof.

Erikson US patent No. 5269747

The Erikson device relates to pulsed electromagnetic field therapy for application to a target area of the skeletal system. Specifically the Erikson device as defined in the claims is designed for electromagnetic field therapy of the spine of a patient's body.

The present invention as claimed is not concerned with therapy of the spine or skeletal system. There is no teaching in Erikson of application of ultrasonic vibrations to the neck of a person. The nature of the construction described in the Erikson embodiment is such that it would be unsuitable for application to the neck.

The transducers of Erikson are wound coils. Transducers are provided on opposite side of the body. Erikson is concerned with applying electromagnetic fields to the body generated by coils, and not with the generation of ultrasonic vibrations. The present invention does not use the application of electromagnetic fields. In Erikson, a pulse output is provided to the electromagnetic coils which energise and de-energise the coils. The pulse signals applied to coils as described in the embodiment at column 6, 9 to 19 comprise a pulse train where the pulses have a duration of 65 microseconds and are turned off for 195 microseconds. This indicates a frequency of less than 4000KHZ, that is a frequency in the acoustic range and not the ultrasonic range.

Erikson thus uses a low frequency electromagnetic field to apply to the body and not ultrasonic vibrations as defined in the claims of the present application.

Erikson thus does not disclose an ultrasonic transducer array as claimed in claim 13, a support for ultrasonic transducers as claimed in claim 14 or flexible mounting of ultrasonic transducers as claimed in claim 15. Similarly

Erikson does not disclose flexible mounting means for mounting ultrasonic transducers as claimed in claim 16 nor adjustment means between ultrasonic transducers which allows the transducers to be adjusted to suit the neck of a person as claimed in claim 17. Erikson does not disclose a main body which houses ultrasonic generation means as claimed in claim 18 but only an electronics module mounted to one of the transducers. Erikson further does not disclose a detachable applicator assembly mounted to the body carrying ultrasonic generation means as claimed in claim 19.

The transducers of Erikson appear to be constructed with respective arcuate members which are connected by flexible belts. The transducers are not mounted at spaced apart positions along an arcuate member as claimed in claim 20. There is no reference in Erikson to contact sensing means for sensing contact between a transducer and neck as claimed in claim 21 as contact is not important in Erikson as it uses electromagnetic fields for therapy rather than ultrasonic vibrations.

As Erikson is not concerned with the application of ultrasonic vibrations to the neck of a person or animal, it does not disclose the invention as claimed in claim 23 nor claims 24 to 28 appended thereto.

A combination of Hughes, Schechter and Erikson, assuming that such a combination is feasible, absent a teaching, suggestion, or motivation to do so, would therefore not result in the invention claimed in claims 13-21, 23-28 and 30-32.

Barnes US patent application No. 2003/0078501

The objection raised by the Examiner in clause 11 is not understood as the Examiner appears to be of the view that the apparatus of the invention is for the purpose of providing "rapid and accurate diagnostics of the location and degree of obstruction in the upper airway of a patient without exposing the patient to any undesired side effects".

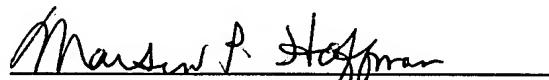
As presented in the specification, and stressed above, the present invention is not for the purposes of diagnosis of the

location and degree of an obstruction in the airway. The present invention is for the purpose of stimulating a coughing reflex. The present invention is not for the purposes of "medical examination procedures" as also referred to by the Examiner in item 11.

The invention of Barnes is for scanning ultrasound and does not have anything to do with respiration or cough stimulation. The apparatus described would not be suitable for application to a person's neck in order to stimulate a cough and therefore it would not be obvious to combine its disclosures with the disclosures of the previously cited documents to produce the invention as claimed in claim 25.

For the several cogent reasons expressed above, and in light of the several novel aspects of applicant's invention, as expressed with varying degrees of specificity, the apparatus claims and the method claims of record, are clearly patentable in content. Prompt, and favorable, consideration of the Amendment is in order.

Respectfully submitted,



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